K022387

SEP 1 9 2002

510(k) SUMMARY
(21 C.F.R. §§ 807.87(h), 807.92)

Applicant/Address: Craftmatic Organization, Inc., 2500 Interplex Drive, Trevose, Pennsylvania 19053, Telephone: (215) 639-1310, Fax: (215) 639-4210

Contact Person/Telephone: Paul D. Rubin, Esq., Patton Boggs LLP, counsel to Craftmatic Organization, Inc., Telephone Number: (202) 457-5646, Fax: (202) 457-6315.

Preparation Date: July 22, 2002

Device Trade Name: Craftmatic® Adjustable Beds with Optional Heat and Massage (Family of Devices, *e.g.*, Craftmatic Monaco, Craftmatic Model I, Craftmatic Model II, Craftmatic Model III, and the Craftmatic Classic)

Classification Name: Therapeutic AC-Powered Adjustable Home Use Bed with Optional Powered Heating Pad and Optional Physical Therapy Pulsator (21 C.F.R. § 880.5100).

Legally Marketed Predicate Device: Craftmatic® Adjustable Bed. The Craftmatic® Adjustable Bed was initially cleared by FDA on June 13, 1984 (K840787B).

Device Description: Craftmatic® Adjustable Beds are electrically powered adjustable beds for home use that adjust into 1001 various positions (*e.g.*, raising the torso, the legs, or both to various heights). The beds have three primary components: (1) a steel bed frame with lift motors, (2) a mattress, and (3) a pendant control. Powered heating pads, which cover the entire mattress, and physical therapy pulsators (built-in massage units) are optional.

Intended Uses: (A) Uses already cleared by FDA include the following: (1) May Provide Temporary Relief of Low Back Pain; (2) May Provide Temporary Relief of Minor Aches and Pains Due to Muscular Fatigue or Overexertion; (3) May Provide Temporary Relief of Edema or Swelling of the Legs; and (4) May Provide Temporary Relief of Poor Local Blood Circulation of the Legs. (B) New uses include the following: (1) Temporary Relief from the Symptoms of Hiatus Hernia; (2) Temporary Relief from the Symptoms of Gastric Reflux; (3) Temporary Relief of Nighttime Heartburn; (4) The Optional Heating Accessory Provides Temporary Relief from Mild Arthritis and Joint Pain, as well as Muscle Pain Associated with Stress and Tension; and (5) Sleeping in an Upright Position May Reduce or Ease Light and Occasional Snoring.

Technological Comparison of "New" Device and Predicate Device: The "new" Craftmatic® Adjustable Beds are essentially identical to the predicate Craftmatic® Adjustable Beds that were cleared by FDA on June 13, 1984. The "new" and predicate beds share the same general structural and functional features. The new indications for use, for which Craftmatic is currently seeking clearance, are similar to, based upon the same

principles as, and substantially equivalent to the indications for use for the predicate bed. Both the "new" and the predicate Craftmatic® Adjustable Beds are electrically powered adjustable beds for home use that adjust into 1001 various positions (*e.g.*, raising the torso, the legs, or both to various heights). The beds have three primary components: (1) a steel bed frame with lift motors (Hubbell Linear Actuators (also known as Gearmaster Linear Actuators), (2) a mattress, and (3) a pendant control. Powered heating pads, which cover the entire mattress, and physical therapy pulsators (built-in massage units) are optional. However, the "new" beds, which are currently on the market, have some minor technological upgrades (*e.g.*, memory positioning in the pendant control, timers for the heat and massage, and improvements in the quality of the mattress construction (*i.e.*, padding and ticking)).

Conclusion: Based upon the foregoing, Craftmatic Organization, Inc. believes that the "new" Craftmatic® Adjustable Beds are substantially equivalent to the predicate Craftmatic® Adjustable Beds.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 19 2002

Craftmatic Organization, Incorporated
C/O Mr. Paul D. Rubin
Patton Boggs LLP
2550 M Street, N.W.
Washington, D.C. 20037

Re: K022387
Trade/Device Name: Craftmatic Adjustable Beds with Optional Heat and Massage (Family of Devices, e.g., Craftmatic Monaco, Craftmatic Model I, Craftmatic Model II, Craftmatic Model III, and the Craftmatic Classic)
Regulation Number: 880.5100
Regulation Name: AC-Powdered Adjustable Hospital Bed
Regulatory Class: II
Product Code: LLI
Dated: July 22, 2002
Received: July 23, 2002

Dear Mr. Rubin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K022387

510(k) Number (if known): _____

Device Name: Craftmatic Adjustable Beds with Optional Heat and Massage (Family of Devices, *e.g.*, Craftmatic Monaco, Craftmatic Model I, Craftmatic Model II, Craftmatic Model III, and the Craftmatic Classic)

Indications for Use:

(1) May Provide Temporary Relief of Low Back Pain;

(2) May Provide Temporary Relief of Minor Aches and Pains Due to Muscular Fatigue or Overexertion;

(3) May Provide Temporary Relief of Edema or Swelling of the Legs;

(4) May Provide Temporary Relief of Poor Local Blood Circulation of the Legs;*

(5) May Provide Temporary Relief from Symptoms of Hiatus Hernia;

(6) May Provide Temporary Relief from the Symptoms of Gastric Reflux;

(7) May Provide Temporary Relief of Nighttime Heartburn;

(8) The Optional Heating Accessory Provides Temporary Relief from Mild Arthritis and Joint Pain, as well as Muscle Pain Associated with Stress and Tension; and

(9) Sleeping in an Upright Position May Reduce or Ease Light and Occasional Snoring.**

* Claims 1-4 have already been cleared by the FDA via the 510(k) process. *See* March 1989 FDA Letter.

** Claims 5-9 are subject to new clearance.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Patricia Cucinotta
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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